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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,604	12/05/2003	Ronald Alan Coffe	4897.0512870	1573
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FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202			EXAMINER ALI, SHUMAYA B	
			ART UNIT 3771	PAPER NUMBER
			NOTIFICATION DATE 05/16/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/729,604	Applicant(s) COFFEE ET AL.	
	Examiner Shumaya B. Ali	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-63 is/are pending in the application.
- 4a) Of the above claim(s) 61-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/20/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 57-60, drawn to a method of controlling the geometry or shape of comminuted matter produced by electrohydrodynamic comminution of at least one liquid, classified in class 424, subclass 45, and 434; and class 417, subclass 50, and 53.**
- II. Claim 61, drawn to use of an oil-based formulation, classified in class 128, subclass 200.14, 200.16, and 200.24.**
- III. Claims 62 and 63, drawn to a dispensing device, classified in class 128, subclass 200.14, 200.16, and 200.24.**

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related process. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). **In the instant case, the inventions as claimed have materially different mode of operation. Invention I is directed to controlling the geometry or shape of comminuted matter and invention II is directed to use of an oil based formulation, therefore, the process defined in invention I does not require “oil based” comminuted matter. Thus, invention I and II are distinct in their mode of operation.**

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Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)): **In this case, the method of controlling the geometry or shape of comminuted matter can be practiced by altering/incorporating (i.e. altering outlet size or incorporating electromagnetic plate) in a dispensing device, using liquid chromatography techniques, and/or gel electrophoresis. Thus the process as claimed can be practiced by another or materially different apparatus.**

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). **In the instant case the process for using an oil based formulation does not require a dispensing device, therefore the process using the product as claimed can be practiced with another materially different product.**

During a telephone conversation with Steven J. Goldstein on 2 May 2007 a provisional election was made with traverse to prosecute the invention of I, claims 57-60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 61-63 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 57, 58, and 60 are objected to because of the following informalities: in regards to claim 57, "the amount" in line 3 lacks antecedent basis; in regards to claim 58, in line 1, consider writing the full name for PVA and PVP; and in regards to claim 60, consider deleting "an" before alcohol in line 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 57, the language of "the amount of at least one medium to high weight polymer in at least one of the liquid" in lines 2 and 3 is not clear. Applicant's disclosure is not clear with respect to adjusting at least one medium to high weight polymer. From the disclosure it is clear that polymer is added to the liquid, however disclosure is silent on adding a medium to the polymer. Is the medium referring to the

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polymer or a separate component where polymer is added? Appropriate clarification is required.

In regards to claim 59, the language of “adding sufficient polymer” in line 2 is indefinite because what amount/ranges “sufficient” is bound to is not clear. Furthermore, the term “some” in lines 2 and 3 are indefinite because metes and bounds of the term “some” is not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 58, and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Onishi et al. US 5,788,819.

As to claim 57, Onishi discloses a method of controlling the geometry or shape of comminuted matter produced by electrohydrodynamic comminution of at least one liquid (see “when a voltage is applied between the working electrode and the counter electrode, an electric field is formed between the two electrodes. This electric field lets the ionic conductive liquid move” in col.7, lines 64-67), which method comprises controlling or adjusting (see “sample solution and a liquid dispersion of the biological substance in a liquid medium having ionic conductivity are introduced between the gap of an electrode pair, and a periodically changing voltage is applied between the pair of electrodes to agitate the liquid medium to cause an agglutination

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reaction...reaction may be utilized for measuring a concentration of a substance in a liquid sample by detecting the degree of agglutination of the reaction mixture” in col.9, lines 50-67; see also “fine particles (DNA, RNA, polymer) can be controlled by adjusting the concentration of the fine particles in the liquid medium introduced into the cell” in col.16, lines 49-52) the amount of at least one medium to high weight polymer (col.10, lines 5-65 lists numerous polymers including protein, DNA, and RNA that are specified in Applicant’s disclosure page 42, lines 17-27) in at least one of the liquids (see water and alcohol in col.12, lines 1-5).

As to claim 58, Onishi discloses a method according to claim 57, wherein the polymer is PVA (see “the fine particulate organic materials are exemplified by homopolymers and copolymers of vinyl monomers such as...vinyl acetate” in col. 10, line 58-61) or PVP in at least one of the liquids.

As to claim 60, a method according to claim 57, wherein the liquid comprises water and an alcohol (see water and alcohol in col.12, lines 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. US 5,788,819.

As to claim 59, Onishi lacks a method according to claim 57, which method comprises controlling the geometry or shape by adding sufficient polymer to the liquid to cause at least some of the comminuted matter to have a granular form with at least some of the granules having fibrils or tails. **However, Onishi teaches a device and method where a "fine particle"/polymer is adjusted into a liquid medium (see col.16, lines 48-52). Also notice, the end product, matter that are granules with fibrils or tails, is a result of a process, adjusting the concentration of polymer in liquid. One of ordinary skill in the art could have arrived at the end product as claimed while in the process of adjusting the concentration of fine particle/polymer into the liquid**

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medium using Onishi's device. Therefore, claimed method step would have resulted from using Onishi's device.

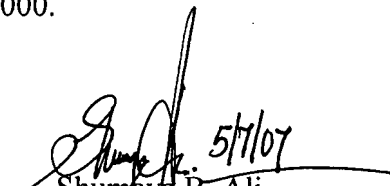
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Flickinger (US 5,906,198) is cited to teach nasal nebulizer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner


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5/10/07